



# 3

Patent Application  
Attorney's Docket No. 4430-57

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Yasmin WADIA and Scott Alan PRAHL

Serial No.: 09/686,594

Filed: October 6, 2000

For: BIOCOMPATIBLE DENATURED ALBUMIN LAMINA  
AND METHOD

Box DAC  
Assistant Commissioner for Patents  
Crystal Park One, Suite 520  
Washington, DC 20231

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JAN 24 2001

**OFFICE OF PETITIONS**

**PETITION FOR FILING PATENT APPLICATION BY  
OTHER THAN ALL THE INVENTORS UNDER 37 C.F.R. 1.47(A)**

Applicant, Scott Alan Prah, hereby petitions the Assistant Commissioner to accept the filing of the above-identified U.S. Patent Application by other than all of the inventors.

Declarations are attached hereto providing proof of the pertinent facts concerning the refusal of a co-inventor to join in the present application for patent. The name and last known address of the co-inventor refusing to join in this application is as follows:

Yasmin Wadia, M.D.  
8181 Fannin Street, #2537  
Houston, Texas 77054

Counsel for Yasmin Wadia, M.D.:

C. Steven McDaniel  
McDaniel & Associates, P.C.  
P.O. Box 2244  
Austin, Texas 78768

01/24/2001 AGOITON 00000020 09686594 130.00 00  
01 FC:122

The invention was developed under the sponsorship of Providence Health System--Oregon ("Providence") by Scott Alan Prah ( "Prah"), employee of Providence, and Yasmin Wadia ("Wadia"), a researcher under contract to Providence at all times relevant.

Prah and Wadia have contractual obligations to assign their inventions to Providence. Accordingly, Providence is entitled to clear title to the invention and to the above-identified patent application and any patent which issues thereon.

The U.S. Supreme Court, in *Solomon v. U.S.*, 137 U.S. 342, 346 (1890), held:

If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he cannot, after successfully accomplishing the work for which he was employed, plead title thereto as against his employer. That which he has been employed and paid to accomplish becomes, when accomplished, the property of his employer. Whatever rights as an individual he may have had in and to his inventive powers, and that which they are able to accomplish, he has sold in advance to his employer.

It is clear that a contracted researcher who is paid to develop an invention comes within the scope of the language cited and is considered as an employee who has been paid in advance to develop the invention. *See In re Hobbs*, 136 U.S.P.Q. 489 (Atomic Energy Comm. Pat. Comp. Bd. 1963).

The Providence-Wadia research contract contains a provision requiring Wadia to assign to Providence all inventions, patent applications and patents issuing thereon arising within the scope of services provided under this contract. The subject matter of the present application was invented within such scope. Furthermore, the present application claims priority from U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999, which discloses the invention claimed in the present application. Wadia and Prah jointly executed an assignment to Providence of the entire interest in the invention disclosed in that application.

Since Wadia was employed by Providence, that is, paid compensation to jointly develop, with Prah1 the biocompatible albumin lamina and method, the invention belongs to Providence and each individual inventor who contributed to the development of the invention has a duty to jointly execute an application for patent covering the lamina and method and to assign the invention, patent application, and any patent which issues thereon to Providence.

In view of the refusal of co-inventor Wadia to execute the papers required for filing the present patent application, Prah1 is believed to be entitled to make such application on behalf of and as agent for his co-inventor (Wadia). Providence, assignee of the entire interest and right in the subject matter of the present application, joins in this Petition.

Accordingly, filing of the application without Wadia's signature is requested.

The required fee pursuant to 37 C.F.R. 1.17(i) is enclosed.



20575

PATENT TRADEMARK OFFICE

MARGER JOHNSON & McCOLLOM, P.C.  
1030 S.W. Morrison Street  
Portland, Oregon 97205 (503) 222-3613

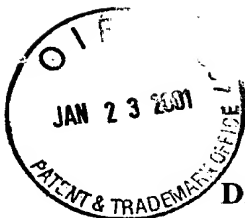
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Box D-6, Assistant Commissioner for Patents, Washington DC 20231 on January 18, 2001.

Signature

Respectfully submitted,

MARGER JOHNSON & McCOLLOM, P.C.

Alexander C. Johnson, Jr.  
Reg. No. 29,396



## DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **BIOCOMPATIBLE DYE-IMMUTED ALBUMIN LAMINA AND METHOD**, the specification of which:

☒ was filed on October 6, 2000, as Application Serial No. 09/686,594.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: None

I hereby claim the benefit under Title 35, United States Code, Sec. 119(e) of any United States provisional application listed below:

Provisional Application No.  
60/158,666

Filing Date  
October 8, 1999

I hereby claim the benefit under Title 35, United States Code, Sec. 120 of any United States application(s), or Sec. 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application: None

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

---

**Full name of first inventor:** Yasmin Wadia

**Inventor's signature:**

Scott Alan Pahl  
(Scott Alan Pahl, Ph.D.,  
on behalf of Yasmin Wadia, M.D.)

1/9/01  
(Date)

**Residence:**

Houston, Texas

**Citizenship:**

India

**Post Office address:**

8181 Fannin Street, Apartment 2537  
Houston, Texas 77054

**Full name of second inventor:** Scott Alan Prah

**Inventor's signature:**

Scott Alan Prah

1/9/01  
(Date)

**Residence:** Portland, Oregon

**Citizenship:** United States

**Post Office address:** 4014 N.E. Knott  
Portland, Oregon 97212

**Assignee of Entire Right:** Providence Health System—Oregon

Assignee's signature:

John V. Fletcher  
John V. Fletcher, Director, Health Integration  
SERVICES

1-11/01  
(Date)

State of Incorporation: Oregon

Post Office address: St. Vincent Hospital and Medical Center  
9205 S.W. Barnes Road  
Portland, Oregon 97225

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yasmin WADIA and Scott Alan PRAHL

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OFFICE OF PETITIONS

DECLARATION OF JOHN V. FLETCHER

John V. Fletcher, being duly sworn, and having personal knowledge of the facts set forth herein, hereby deposes and says that:

1. I am Director of Health Integration Services for Providence Health System—Oregon (“Providence”) of Portland, Oregon.
2. At all times relevant, Yasmin Wadia, M.D. (“Dr. Wadia”) was under contract as a research fellow to Providence to provide services, including research, intellectual activity and/or technical services, in the development of biomedical laser-based coronary surgical procedures.
3. Pursuant to Dr. Wadia’s fellowship, Dr. Wadia signed an Invention, Confidentiality, and Non-Disclosure Agreement (“Agreement”). *See Petition Ex. D, Providence Health System Invention, Confidentiality, and Non-Disclosure Agreement.* The Agreement includes a provision obligating Dr. Wadia to assign all rights in inventions, improvements, discoveries, works and ideas that result from work performed by Dr. Wadia for Providence. The Agreement further obligates Dr. Wadia to execute U.S. and foreign



patent applications and any other legal documents necessary to transfer title therein to Providence. *See Petition Ex. D*, ¶ 4.

4. Providence received an Invention Disclosure Form, titled "Technology for laser fusion of solid visceral organs (liver, spleen, and kidney)", on June 25, 1999 and jointly filed by Wadia and Scott Alan Prah, Ph.D. ("Dr. Prah"). *See Petition Ex. A*. In that Form, Drs. Wadia and Prah listed themselves as co-inventors and as jointly conceiving of the invention.

5. Providence received an Invention Disclosure Form, titled "Denatured Albumin Lamina", on August 25, 1999 and jointly filed by Drs. Wadia and Prah. *See Petition Ex. B*. In that Form, Drs. Wadia and Prah listed themselves as co-inventors, as jointly conceiving the invention and jointly making the first written description of the invention.

6. The subject matter of the above-referenced Invention Disclosure Forms was the subject matter of U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999 and incorporated by reference. Co-inventors Wadia and Prah jointly executed an assignment, *Petition Ex. C*, to Providence of the entire right and interest in the invention, application, and any resulting patent on October 14, 1999. The assignment was duly recorded in the U.S. Patent and Trademark Office on June 27, 2000 at Reel 010954/Frame 0821. *See Petition Ex. C*.

7. A Request for Filing a Provisional Patent Application and a copy of the Assignment were filed with the above-identified U.S. Provisional Application, of record in the present application. Drs. Wadia and Prah named themselves as co-inventors in both of these documents.

8. Providence believes, based on the foregoing, that Drs. Wadia and Prah are original, first and joint inventors of the invention disclosed in U.S. Provisional Patent

Application Serial No. 60/158,666 and claimed in U.S. Patent Application Serial No. 09/686,594.

9. Providence believes, based on the foregoing, that it holds legal and/or equitable title to the entire interest and rights of the invention disclosed in U.S. Provisional Patent Application Serial No. 60/158,666 and claimed in U.S. Patent Application Serial No. 09/686,594.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED this 11 day of January, 2001.

Respectfully submitted,

  
John V. Fletcher

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yasmin WADIA and Scott Alan PRAHL

Serial No.: 09/686,594

Filed: October 6, 2000

For: BIOCOMPATIBLE DENATURED ALBUMIN LAMINA  
AND METHOD

Box DAC  
Assistant Commissioner for Patents  
Crystal Park One, Suite 520  
Washington, D.C. 20231



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JAN 24 2001

OFFICE OF PETITIONS

DECLARATION OF SCOTT ALAN PRAHL

Scott Alan Prahl, being duly sworn, and having personal knowledge of the facts set forth herein, hereby deposes and says that:

1. I am employed as a Senior Research Scientist by Providence Health System—Oregon (“Providence”) of Portland, Oregon, under an employment contract by which I am obligated to assign my interest in any invention I make or to which I contribute.
2. I am one of the inventors of the invention disclosed and claimed in the U.S. Patent Application referenced above.
3. Prior to November 1999, I developed and tested, jointly with Yasmin Wadia, M.D. (“Wadia”), a biocompatible albumin lamina and method for its use in repairing a lesion on a solid visceral organ.
4. Wadia and I jointly completed and filed an Invention Disclosure Form, titled “Technology for laser fusion of solid visceral organs (liver, spleen, and kidney)”, on June 25, 1999. *See Petition Ex. A.* In that Form, Wadia and I listed ourselves as joint inventors and stated that we jointly conceived of the invention.

5. Wadia and I jointly completed and filed an Invention Disclosure Form, titled "Denatured Albumin Lamina", on August 25, 1999. *See Petition Ex. B.* In that Form, Wadia and I listed ourselves as joint inventors, and we stated that we jointly conceived of the invention and jointly made a written description of the invention.

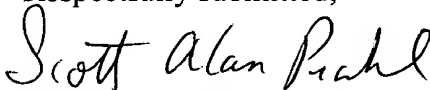
6. The subject matter of the above-referenced Invention Disclosure Forms was the subject matter of U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999. Wadia and I, as co-inventors, jointly executed to Providence an assignment, *Petition Ex. C*, of the entire interest in the invention, application, and any resulting patent on October 14, 1999. The assignment was duly recorded in the U.S. Patent and Trademark Office on June 27, 2000 at Reel 010954/Frame 0821. *See Petition Ex. C.*

7. A Request for Filing a Provisional Patent Application was filed with the above-identified U.S. Provisional Application and is of record in the present application. Wadia and I are named as co-inventors in the Request.

8. Based on the foregoing, I believe that Wadia and I are co-inventors of the subject matter disclosed in the present application, U.S. Patent Application Serial No. 09/686,594.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED this 9 day of January, 2001.

Respectfully submitted,  
  
Scott Alan Prah



## PROVIDENCE HEALTH SYSTEM INVENTION DISCLOSURE FORM

### 1. Descriptive title:

Technology for laser fusion of solid visceral organs ( liver, spleen and kidney)

### 2. Inventor(s):

a) First Name: Yasmin

Last Name: Wadia

Title: MD

Institution: Oregon Medical Laser Center, 9205 SW Barnes Rd, Portland, Oregon

Office Phone No: (503) 216 6828

Office Fax No: (503) 216 2422

Home Address: 380, NW Island Circle, Apt B-4 Beaverton, Oregon 97006

Home Phone No: (503) 690 8293

Citizenship: Indian

Nature of Involvement: Conception and practical surgical application.

Contribution (%): 50 %

b) First Name:

Middle Name:

Last Name

Title:

SCOTT

ALAN

PRAHL

SR. RESEARCH SCIENTIST

Institution: OMLC

Office Phone No: (503) 216 2197 Office Fax NO: 503 216 -2422

Home Address: 4014 NE KNOTT

Home Phone No: (503) 288-9366 Citizenship: USA

Nature of Involvement: Conception and theory

Contribution (%): 50

### 3. Brief Description of the Invention:

Surgery of solid visceral organs like liver, kidney and spleen have always proved to be a challenge as these organs don't hold sutures well and are difficult to put back together after traumatic rupture. Elective removal of primary or secondary neoplastic lesions from the liver is rarely undertaken as it has a high morbidity and mortality associated with bleeding and biliary leakage and sepsis.

Laser fusion of traumatic rupture of liver, spleen or kidney and /or fusion of large raw surfaces after partial non anatomical liver lobectomy can be achieved by the following technique. Viscous albumin ( 50-53 gm/100dl) solder mixed with indocyanin green dye (photo spectrometric analysis - 40-60  $\text{cm}^{-1}$ ) is spread thinly over the raw surface or into the ruptured edges which are then co-opted manually. A 805nm wave length diode laser is set at 10 Watts, with a pulse width of .1sec and a pulse interval of .1 sec. The albumin -ICG solder is lazed over the target area using a visual feed back system. The next step involves harvesting native free omentum or using heterograft omentum as the circumstances demand. The omentum is layered over the target surface

Ex

A

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of

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**6. Advantages:**

- 1) Trauma Surgery - Can be used to fuse solid visceral organs and seal large raw surfaces with complete hemostasis without sutures in presence of complete coagulation failure.
- 2) Cancer Surgery - Can be used to remove directly invading neoplasms, resect multiple primary or secondary discrete neoplasms which leave large irregular craters.
- 3) Living donor liver lobar transplants - Will decrease the morbidity and increase the ease of doing living related liver lobar resection.

**7. Disadvantages:**

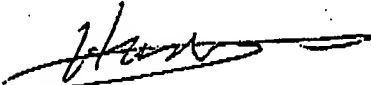
None

**8. Detailed examples and/or drawings for making and using the invention:****9. Utility:**

- 1) Life saving - Quick trauma / battle field control of exsanguinating liver injuries.
- 2) Elective Cancer surgery.
- 3) Living related Liver transplants.

**10. Public Disclosure: None****11. Signatures (Inventor and Witnesses)**

INVENTORS - Scott Pahl 6-25-99  
                  yamin. Wadia 6/25/99

WITNESS -  6/25/99  
                  Liza A. Bunkley 6/25/99

Best Available Copied and did

(4/15/99)

laser welding of liver &  
kidney freshly harvested from  
cotton.

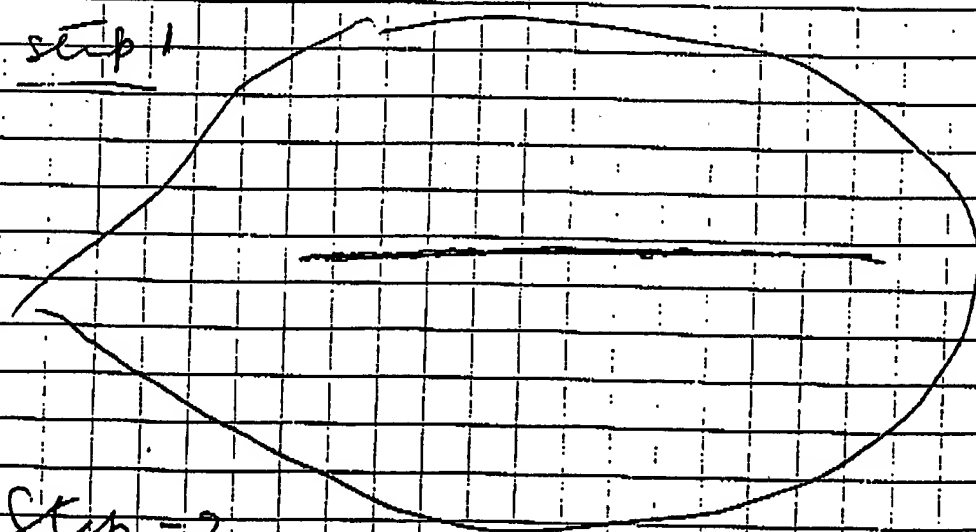
Helped by Dr. Brad Scott and Hwa.

Used 50% Albumin + 1mM ICG  
concentration for surface welding.

Got good weld strength, was  
satisfied.

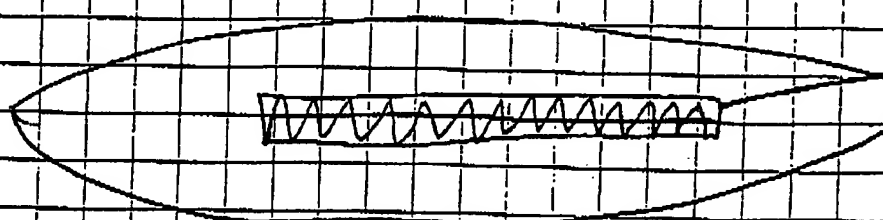
Additional strength achieved  
with ~~150~~ 2.5 mm thick Albumin ICG  
strips over the incision in  
the liver and welded 1cm on  
each side & over the edge.

Step 1



Albumin  
+ ICG  
surface  
weld.

Step - 2



2.5 mm  
thick strip  
of Albumin  
ICG

Yasmin

Ex A

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## LASER FUSION OF LIVER AND SPLEENIC LACERATION - ACUTE FEASIBILITY STUDY

Date : 04-21-99  
Type : Acute Experiment - I  
Animal ID : Pig #997  
Laser: Diomed 25, 25W surgical diode laser, GaAlAs Laser Diode, wavelength 800nm  
Surgeons : Wadia/Kajitani  
Laser scientist: Dr. Scott Prah  
Assistants : Kuong/Monica/Lisa  
Anesthesia : GA with ETT, Isoflurane.  
Procedure : After proper identification of the animal, anesthesia was induced with Telazole 8mg/Kg I/M. Isoflurane was given by face mask and the animal was intubated with a size 5 F cuffed endotracheal tube.

The animal was used for another experiment and was utilized by us prior to euthanasia.

The abdomen was opened using a right subcostal incision that was later extended across the midline and transversely onto the left side to facilitate exposure. The portahepatis was occluded using pringle's maneuver and the time was noted. Two liver lacerations were made one on the right lobe and one on the left lobe. A 5cm long and 3cm deep incision was made on the left lobe of the liver and the hepatic-portal sinuses (5-7mm in diameter) were exposed. An incision 3cm long and 1cm deep was made on the right lobe of the liver. The 800nm diomed-25W pulsed surgical laser was set at 10 Watts with 100msec pulses or 5 Hz (1Joule energy pulses / 5 times a second). Fifty- percent human albumin with .1mmol of ICG was squirted into the incision. The edges were co-opted manually with finger pressure and lazing the liquid solder fused the incision. An ICG albumin solid solder .25mm thick wafer was layered over the surface of the liver 1cm on each side of the incision. The wafer was fused to the surface of the liver. The clamp on the portahepatis was released and the time noted.

An incision 3cm long and through 2/3 of the thickness of the spleen was made. Laser fusion similar to the method used above was used. After a brief waiting period of about 30 minutes the animal was sacrificed and the liver specimen was preserved in formalin and sent for histopathology. The spleen specimen was kept in saline and inspected the next morning for dehiscence.

Yasmin Wadia, M.D

Ex A  
Page 5 of 5

TOTAL P. 10

**PROVIDENCE HEALTH SYSTEM  
INVENTION DISCLOSURE FORM**



1. Descriptive title  
Denatured Albumin lamina

2. Inventor(s):

a) First Name: Yasmin Last Name: Wadia  
Title: Surgical Research Fellow

Institution: Oregon Medical Laser Center, 9205 SW Barnes Rd, Portland, Oregon  
Office Phone No: (503) 216 6828 Office Fax No: (503) 216 2422  
Home Address: 380, NW Island Circle, Apt B-4 Beaverton, Oregon 97006  
Home Phone No: (503) 690 8293 Citizenship: Indian  
Nature of Involvement: Conception, preparation and practical surgical application.  
Contribution (%): 50 %

b) First Name: Scott Middle Name: Alan Last Name: Prah  
Title: Sr. Research Scientist

Institution: Oregon Medical Laser Center, 9205 SW Barnes Rd, Portland, Oregon

Office Phone No: (503) 216 2197 Office Fax NO: (503) 216 2422  
Home Address: 4014 NE Knott  
Home Phone No: (503) 288 9366 Citizenship: USA  
Nature of Involvement: Conception, practical application  
Contribution (%): 50%

3. Brief Description of the Invention:

This invention is linked to 'Laser Fusion of solid visceral organs' patent. It is a new biomaterial which will be used as a temporary scaffold, in the same way that porcine omentum was utilized.

This biomaterial is made of a solid sheet of pure 47-57% denatured human albumin. The thickness of this material varies from 250 $\mu$  to 2mm depending on the application. On gross examination, it looks a transparent amber sheet and on handling it, it is very pliable, contours easily and is insoluble in water. Its tensile strength would vary with its thickness and that parameter is still to be quantified.

The method for preparing is as follows:

Twenty five percent human albumin is dehydrated to a concentration of 47-57% (gm/100dl). A small quantity is interspersed between two plastic, teflon, glass or metal sheets that are mounted with specific distance spacers to produce the desired sheet thickness. This contraption is placed within a water-tight compartment that is then immersed in hot water maintained between 80-90 degrees centigrade for 1 minute. The denatured sheet is removed, double packaged and gamma sterilized.

#### 4. Existing Documentation

##### a) Invention Records:

Item	Conception	First Written Description or Flow Sheet	First Successful Operation/ Demonstration of Efficacy
Date	08-24-99	08-25-99	In- vitro laser fusion to the liver- 08-24-99
By Whom	Yasmin Wadia, Scott Pahl	Yasmin Wadia, Scott Pahl	Yasmin Wadia
Where Recorded	This disclosure	This disclosure	This disclosure
To Whom 1 <sup>st</sup> Disclosed	Lisa Buckley Hua Xie	This disclosure	Lisa Buckley Tim Denison
Date First Disclosed	08-24-99	08-25-99	08-25-99

##### b) Copies of pertinent documentation:

#### 5. Background

Patent	Inventor	Issued	Title
5,929,044	Poppas	July 27, 1999	Protein solder composition and method of use
5,824,015	Sawyer	Oct 20, 1998	Method for Welding Biological tissue
5,749,895	Sawyer	May 12, 1998	Method for bonding or fusion of biological tissue and material.
5,552,452	Khadem	Sept 3, 1996	Organic tissue glue for closure of wounds
5,209,776	Bass, et al	May 11, 1993	Tissue bonding and sealing composition and method of using the same

#### References:

- 1) Small W 4<sup>th</sup>, Heredia NJ, et al. Dye-enhanced protein solders and patches in laser-assisted tissue welding. J clin Laser Med Surg 1997;15(5):205-8
- 2) Lauto A. Repair strength dependence on solder protein concentration: a study in laser tissue tissue welding.

- 3) Lauto A, Poppas DP, et al. Solubility study of albumin solder for laser tissue welding.  
Laser surg Med 1998;23(5):258-62.

**6. Advantages:**

- Human albumin is completely biocompatible and is commercially available.
- Denatured albumin sheets are insoluble in water, transparent and pliable.
- They are easily sterilized and stored.
- They can be impregnated with a chromophore throughout or on the surface only.
- They can be impregnated with antibiotics if used in an infected situation.

**7. Disadvantages:**

No disadvantages have been discovered yet.

- 8. Detailed examples and/or drawings for making and using the invention:**  
Refer patent and manuscript on Laser fusion of solid visceral organs.

**9. Utility:**

- Biomaterial scaffold for Laser Fusion of solid visceral organs.
- Can be used to make an air/water tight or hemostatic seal for suture line re-enforcement.
- Impregnated with antibiotics it can be used for temporary external integument replacement in burns or areas of extensive tissue loss.

- 10. Public Disclosure: None done.**

**11. Signatures (Inventor and Witnesses)**

INVENTORS -

*Yasmin . Wadia*  
*Scott Patel*

8/25/99

WITNESSES -

*Wadia*  
*Chitra Ray*

Ex

B

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of 3



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APRIL 06, 2000

PTAS

MARGER JOHNSON & MCCOLLOM, PC.  
ALEXANDER C. JOHNSON, JR.  
1030 S.W. MORRISON STREET  
PORTLAND, OREGON 97205



**COPY**

UNITED STATES PATENT AND TRADEMARK OFFICE  
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 12/20/1999

REEL/FRAME: 010504/0702  
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

WADIA, YASMIN

DOC DATE: 10/14/1999

ASSIGNOR:

PRAHL, SCOTT ALAN

DOC DATE: 10/14/1999

ASSIGNEE:

SISTERS OF PROVIDENCE IN OREGON  
520 PIKE STREET  
P.O. BOX 11038  
SEATTLE, WASHINGTON 98111-9038

SERIAL NUMBER: 60158666

FILING DATE: 10/08/1999

PATENT NUMBER:

ISSUE DATE:

DIANE RUSSELE, PARALEGAL  
ASSIGNMENT DIVISION  
OFFICE OF PUBLIC RECORDS

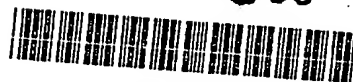
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01-31-00

PATENTS ONLY  
orney's Do. No. 4430-57

COPY

1999 DEC 20 AM 11:37



101254220

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OPR/FINANCE

In re application of:  
YASMIN WADIA and  
SCOTT ALAN PRAHL

Serial No. 60/158,666

Filed: October 8, 1999

For: LIVER REPAIR USING LASER SOLDERING  
OF ALBUMIN IN A PORCINE MODEL

Box Assignment  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

I HEREBY CERTIFY THAT THIS COR-  
RESPONDENCE IS BEING DEPOSITED  
WITH THE UNITED STATES POSTAL  
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☐ ASSISTANT COMMISSIONER FOR  
TRADEMARKS, 2900 CRYSTAL DRIVE,  
ARLINGTON VA 22202-3513

ON 12/21/1999  
*[Signature]*

Please record the attached original document or copy thereof and return the recorded instrument to the undersigned.

1. Name of party(ies) conveying an interest: (1) YASMIN WADIA, 380 N.W. Island Circle, Apartment B-4, Beaverton, Oregon 97006; (2) SCOTT ALAN PRAHL, 4014 N.E. Knott, Portland, Oregon 97212
2. Name and address of party(ies) receiving an interest: SISTERS OF PROVIDENCE IN OREGON, an Oregon Nonprofit Corporation, 520 Pike Street, P.O Box 11038, Seattle, Washington 98111-9038
3. Description of the interest conveyed: Assignment

Date of execution of attached document: October 14, 1999

4. Application number(s) or patent number(s). 60/158,666 Additional sheet attached? No
5. Name and address of party to whom correspondence concerning document should be mailed:

MARGER JOHNSON & McCOLLOM, P.C.  
1030 S.W. Morrison Street  
Portland, Oregon 97205  
Telephone: (503) 222-3613

6. Number of applications and patents involved: 1
7. Enclosed is our check for \$40.
8. Any deficiency or overpayment should be charged or credited to deposit account number 13-1703.
9. To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Customer No. 20575

01/28/2000 DNGUYEN 00000120 60158666

01 FC:581

40.00 DP

Dated: 14 Dec 1999

Respectfully submitted,

MARGER JOHNSON & McCOLLOM, P.C.

By *[Signature]*  
Alexander C. Johnson, Jr.  
Registration No. 29,396

MARGER JOHNSON & McCOLLOM, P.C.  
1030 S.W. Morrison Street  
Portland, Oregon 97205  
Telephone: (503) 222-3613

Total number of pages comprising cover sheet and attached assignment: 4

Ex C  
Page 3 of 6

ASSIGNMENT

COPY

Assignor: YASMIN WADIA  
380 N.W. Island Circle  
Apartment B-4  
Beaverton, Oregon 97006

SCOTT ALAN PRAHL  
4014 N.E. Knott  
Portland, Oregon 97212

Assignee: SISTERS OF PROVIDENCE IN OREGON,  
an Oregon Nonprofit Corporation,  
520 Pike Street  
P.O Box 11038  
Seattle, Washington 98111-9038

Title of  
Invention: LIVER REPAIR USING LASER SOLDERING  
OF ALBUMIN IN A PORCINE MODEL

U.S. Patent Application:

Application Serial No.: 60/158,666

Filing Date: October 8, 1999

For good and valuable consideration, the receipt of which is hereby acknowledged, the above-named Assignor hereby sells, assigns and transfers to Assignee, the full and exclusive right, title and interest in and to the above-identified invention, patent application and patent rights throughout the world, including foreign patent priority rights; said invention, application and letters patent in this or any foreign country, and all divisions, continuations, reissues and extensions thereof, to be held and enjoyed by Assignee, for its own use and benefit, and for its successors and assigns to the full end of the term for which letters patent may be granted in this or any foreign country, as fully and entirely as the same would have been held by Assignor had this assignment and sale not been made, and covenant that Assignor has full right so to do, and agree that Assignor will communicate to Assignee, or its successors and assigns, any facts known to Assignor respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, and do everything possible to aid Assignee, its successors and assigns to obtain and enforce proper patent protection for said invention in this or any foreign country.









RECEIVED  
JUL 08 1998  
HUMAN RESOURCES

**PROVIDENCE HEALTH SYSTEM  
INVENTION, CONFIDENTIALITY, AND NON-DISCLOSURE AGREEMENT**

The undersigned has been engaged to perform services that may include research, intellectual activity and/or other technical services for the Sisters of Providence in Oregon dba Providence Health System ("Providence"), 1235 NE 47<sup>th</sup>, Portland, OR 97213. For the purpose of this agreement, persons "engaged" by Providence include but are not limited to, employees, students, contractors, collaborators, research assistants and/or research fellows. This agreement does not constitute an employment agreement and does not define any rights, obligations, or status of the undersigned in regards to Providence except for the intellectual property rights as set forth below.

In consideration of the undersigned's original and continuing engagement with Providence in a capacity in which he or she may produce or come into contact with proprietary information, the undersigned acknowledges Providence's ownership rights in such proprietary information and the need to safeguard the proprietary information from disclosure to competitors and others not engaged by Providence.

The undersigned therefore agrees as follows:

1. For purposes of this Agreement, "Proprietary Information" shall mean any information or material which is proprietary to Providence, or designated as Proprietary Information by Providence and not generally known by non-Providence personnel, to which the undersigned obtains knowledge or access as a result of the undersigned's relationship with Providence, including information conceived, originated, discovered or developed in whole or part by the undersigned. Proprietary Information includes, but is not limited to, the following forms of information, including technical information and other information of a similar nature (whether or not reduced to writing): discoveries, ideas, concepts, designs, drawings, specifications, techniques, computer flow charts and programs, models, data, documentation, diagrams, research, development, processes, procedures, "know-how", marketing techniques, past and prospective customers, cost data, pricing policies and financial information. Proprietary Information also includes any information described above which Providence obtains from another party and which is designated as Proprietary Information.
2. The undersigned shall turn over to Providence all originals and all copies of materials containing Proprietary Information in the undersigned's possession, custody or control upon request, or upon termination of the undersigned's engagement with Providence. The undersigned agrees to attend a termination interview with a manager of Providence to confirm turnover of such materials and to discuss any questions the undersigned may have about his or her continuing obligation under this agreement.
3. The undersigned shall, during his or her engagement by Providence and thereafter, hold in confidence and not disclose, communicate or transmit to unauthorized persons or use for unauthorized purposes any Proprietary Information.
4. Any inventions, improvements, discoveries, copyrightable works, or ideas conceived, developed or made by the undersigned in whole or in part during any term of his or her relationship with Providence, whether during business hours or otherwise, that relate to Providence's business, or that are made using any Providence equipment, facilities, materials, labor, money, time or other resources or that result from any work performed by the undersigned for Providence, shall belong exclusively to Providence and shall be deemed Proprietary Information for purposes of this Agreement. The undersigned agrees to communicate promptly to Providence any and all such inventions, improvements, discoveries, works and ideas and, upon

request, to execute U.S. and foreign patent applications and any other legal documents necessary to transfer title therein to Providence, and to assist Providence in any proper manner in obtaining and enforcing intellectual property rights at Providence's expense.

5. Because of the unique nature of the Proprietary Information, the undersigned understands and agrees that if the undersigned fails to comply with any of his or her obligations under Sections 2, 3, or 4 above, monetary damages will be inadequate to completely compensate Providence for such breach. Accordingly, the undersigned agrees that Providence will, in addition to any other remedies available to it at law or in equity, be entitled to preliminary and permanent injunctive relief to enforce the terms of Sections 2, 3, or 4 above.

6. If any provision of this Agreement, or portion thereof, is determined to be invalid or unenforceable, the remaining provisions shall not be affected, and the Agreement shall be enforced as though the invalid or unenforceable provision, or portion thereof, were not in the Agreement.

7. This Agreement shall be governed by Oregon law. This Agreement contains the full and complete understanding of the parties with respect to the subject matter hereof and supersedes all prior representations and understandings, whether oral or written.

8. Should the undersigned wish to disclose any Proprietary Information for any purpose, he or she shall, at least 30 days prior to the date of the desired disclosure, submit a written request, stating the purpose of the disclosure, along with a copy of the Proprietary Information sought to be disclosed, to the Director of the appropriate research center. The Director, in his or her sole discretion, may authorize the disclosure of such Proprietary Information.

I have read, understand, and agree to the above terms and acknowledge receipt of a copy of this agreement.

Date: 7/2/98 SS# 541-49-5391

Signature: Yasmin Wadia

Name (printed): YASMIN. WADIA

Mailing Address: 9205, SW, BARNES ROAD - PORTLAND  
(OMLC) OR-97225

Scott Prahl, PhD,  
Senior Research Scientist  
Oregon Medical Laser Center  
9205 SW Barnes Rd,  
Portland, OR – 97225

Dear Scott,

Let me just get to the point and let the facts speak for themselves.

During the past two weeks I've come to realize that I erred when I included you as co-inventor on two of my patent disclosures, a) A Surgical Methods Patent – Laser Fusion of solid visceral organs and b) A biomaterial Patent – Denatured Albumin Lamina. At that time I did not understand inventor validation rules and did not have the information I now possess.

To state the facts and chain of events leading to the surgical methods patent – Laser Fusion of solid visceral organs.

- 1) The idea to use laser welding with albumin solder to repair liver, spleen or kidney was solely mine conceptualized on 04/15/99 and communicated to you and Dr. Xie. I did not invent laser welding technology, I just identified a possible application.
- 2) On 04/19/99 I did the first in-vitro experiment using 50% albumin solder mixed with 0.1mmol of ICG. This was witnessed by Dr. Gregory, Dr. Xie and David Spain. At this time I used a solid strip of Albumin-ICG as a scaffold. I used the Diomed laser, optimized the setting to 10 Watts with a pulse width of 100msec and a pulse interval of 100msecs giving an average power of 3.5 watts.
- 3) After the success of the bench top experiments I made up the a batch of albumin- ICG which was 50% albumin with ICG ( photo spectrometric analysis –  $50\text{ cm}^{-1}$ ).
- 4) I did a series of 18 acute liver repair experiments using laser welding from 04/21/99 to 06/24/99 and 5 acute kidney repair experiments using laser soldering from 05/11/99 to 05/21/99.

I therefore conceived and reduced to practice laser soldering to repair liver and kidney. I did not know that what I was doing was patentable, until Andrew Barofsky visited our lab and advised me to write a disclosure. I included your name as you were the senior laser scientist in the lab and I considered you a mentor and an important author on my paper.

Regarding the facts relating to the biomaterial patent on denatured albumin.

I realized after my chronic experiments that I needed to develop a biomaterial to use as a scaffold in human beings as human omentum was very fatty and probably could not be used as a scaffold.

On 08/24/99 encouraged by you to try and make denatured albumin patches using solid 60-70% albumin solder as done by Karen MacNeally, I conceived and produced denatured albumin sheets using an entirely new method using 50% liquid albumin solder spread between two plastic sheets and denatured it in a water bath at 90 degrees centigrade for 1 minute. This method produced a transparent insoluble albumin sheet which varied from 89 $\mu$ m to 300 $\mu$ m in thickness. I wrote up the invention disclosure and included you as I regarded you as my mentor in this area.

During the last two weeks, I have realized that I made a mistake to confuse your role as a mentor as being a co-inventor for the above reasons. If you wish to contest the issue, be kind enough to spell out the reasons. We could then bring up the matter to Alex Johnson for arbitration and his legal council.

Yours truly,



Yasmin Wadia, MD

Cardiovascular Surgical Fellow

Oregon Medical Laser center.

Date- 12/6/99

Cc Dr. Kenton Gregory

Cc John Fletcher

Cc Rob Forest

Cc Alex Johnson

YASHIN NADIA  
380 NW ISLAND CIR APT B4  
BEAVERTON OR 97006-8530



ALEX JOHNSON  
MARGER JOHNSON & MCCOLLEEN  
1030 S.W. MORRISON ST.  
PORTLAND, OR - 97205

97205+2226

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yasmin WADIA and Scott Alan PRAHL

Serial No.: 09/686,594

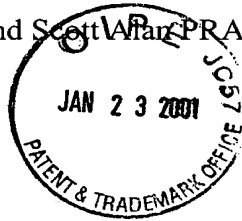
Filed: October 6, 2000

For: BIOCOMPATIBLE DENATURED ALBUMIN LAMINA  
AND METHOD

RECEIVED

JAN 24 2001

OFFICE OF PETITIONS



**DECLARATION OF ALEXANDER C. JOHNSON, JR.**

Alexander C. Johnson, Jr., being duly sworn, and having personal knowledge of the facts set forth herein, hereby deposes and says that:

1. I am a principal of Marger Johnson & McCollom, P.C., a patent law firm.
2. I am an attorney of record for the U.S. Patent Application referenced above, as well as U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999, from which the present application claims priority and which is incorporated by reference, disclosing the invention claimed in the present application. I prepared and directed preparation of the provisional application based on written disclosures submitted jointly by Scott Alan Prah, Ph.D. (Prah) and Yasmin Wadia, M.D. (Wadia), *see Petition Exs. A and B*, and consultation with Prah and Wadia jointly.
3. At the time of filing U.S. Provisional Patent Application Serial No. 60/158,666, I prepared an Assignment, *Petition Ex. C*, in favor of Providence Health System—Oregon (“Providence”) of the entire interest in the invention, provisional application, and any resulting patent. The Assignment was jointly executed by Prah and Wadia on October 14, 1999 and subsequently recorded in the U.S. Patent and Trademark Office on June 27, 2000 at Reel 010954/Frame 0821. *See Petition Ex. C*.
4. On or about December 7, 1999, I received from Wadia a copy of a letter from Wadia to Prah. *See Petition Ex. E*. Despite naming herself and Prah as co-inventors and



executing an Assignment to Providence in which she identified herself and Prah1 as joint inventors, Wadia contests Prah1's designation as co-inventor in the original disclosures and declares herself sole inventor of the invention disclosed in U.S. Provisional Serial No. 60/158,666.

5. I directed preparation of the present application and accompanying formal papers including a Declaration of Inventors, Assignment and Power of Attorney. A complete copy of the application and formal papers were sent via first-class U.S. Mail to Wadia on October 18, 2000. A complete copy of the application and formal papers were sent via first-class U.S. Mail to Prah1 on October 18, 2000. All of the relevant formal papers name Prah1 and Wadia as co-inventors.

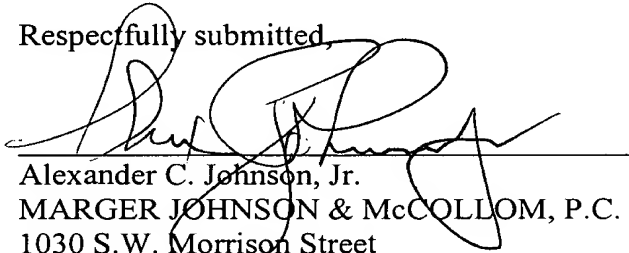
6. On November 6, 2000, I was contacted by C. Steven McDaniels ("McDaniels"), informing me that he represents Wadia. Under the Ethics rules, I could no longer deal directly with Wadia. On November 16, 2000, I sent via first-class U.S. Mail a letter to McDaniels, counsel for Wadia, requesting that Wadia appropriately sign and execute the formal papers and return them to me for filing in the present application. I specifically made clear that time was of the essence in this matter. In subsequent contact with McDaniels and in view of the urgency I had expressed, he made no assertion that his client had failed to receive the formal papers sent on October 18, 2000. McDaniels has indicated to me that Wadia will not sign the Declaration of Inventors, and she has not done so.

7. In view of Wadia's dispute as to joint inventorship of the invention disclosed in the provisional and non-provisional, the silence of McDaniel concerning receipt of formal papers, Wadia's failure to return executed papers to me for filing despite my urgent request for same, and McDaniels' indication that his client, Dr. Wadia, would not join in the application as submitted to her, I reasonably conclude that Wadia's conduct constitutes a refusal to join in the present application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED this 18 day of January, 2001.

Respectfully submitted,



Alexander C. Johnson, Jr.  
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Portland, Oregon 97205  
Telephone (503) 222-3613